

SEP 24 1996

Dr. Eric L. Foxman
Bioforce of America, Ltd.
P.O. Box 507
Kinderhook, New York 12106

Dear Dr. Foxman:

This is in response to your letter of June 21, 1996, which was received by the Food and Drug Administration (FDA) on July 23, 1996, concerning the changes you are making in the statements of nutritional support that you are making pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your letter responds to a letter of June 12, 1996 from the FDA. Your submission states that you are changing the statements for your products to the following:

"Stinging Nettle"

No statement of nutritional support will be made.

"Bronchosan"

Irritated throat or lungs can lead to fits of coughing. The components of A. Vogel's Bronchosan help to soothe the throat and lungs.

As stated in our previous letter, section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for "Bronchosan" suggest that it is intended to treat or mitigate disease, in that, it claims to help "soothe the throat and lungs" and states that "[I]rritated throat or lungs can lead to fits of coughing." Therefore, this claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make a claim of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

We acknowledge your statement that you will add the disclaimer required by section 403(r)(6)(C) of the act to the label for "Gastrosan" at the next printing of the label.

This disclaimer must contain, prominently displayed and in boldface type, the following: "This

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statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

Sincerely yours,

**James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition**

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, New York District Office, Office of Compliance, HFR-NE140

**FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement,
HFC-200**